

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

In re Entresto (sacubitril/valsartan) Patent  
Litigation

C.A. No. 20-md-2930-RGA

NOVARTIS PHARMACEUTICALS  
CORPORATION,

Plaintiff,

v.

C.A. No. 22-1395-RGA

MSN PHARMACEUTICALS INC.,  
MSN LABORATORIES PRIVATE  
LIMITED, MSN LIFE SCIENCES  
PRIVATE LIMITED, GERBERA  
THERAPEUTICS, INC., NANJING  
NORATECH PHARMACEUTICAL CO.,  
LIMITED,

Defendants.

**MSN’S REPLY BRIEF IN OPPOSITION TO  
NOVARTIS’S PROPOSED FINAL JUDGMENT**

## **I. INJUNCTIVE RELIEF IS NOT PROPER IF MSN PREVAILS.**

If the Court finds non-infringement of the '918 patent, Novartis still wants automatic injunctive relief. Illogically, Novartis says this is appropriate because “[a] preponderance of the evidence presented at trial,” (D.I. 514 at 11), demonstrates otherwise. But if the Court rules in MSN’s favor, the record will show precisely the opposite.

Regardless of Novartis’s belief, irreparable harm cannot result from a non-infringing product. Once again, Novartis repeats points from its injunction brief, claiming that harm to MSN is minimal. D.I. 483-484; D.I. 500; D.I. 510. The prior briefing, however, shows that “simply delay[ing]” MSN’s launch for even three business days, (D.I. 514 at 12), can seriously impede MSN’s potential first-mover advantage. In any event, Novartis concedes that “MSN cannot launch before July 16, 2025,” (*id.* at 5); there is no dispute that pediatric exclusivity blocks MSN’s launch. Injunctive relief, even for convenience, remains improper if the Court rules in MSN’s favor.

## **II. DEFECTS PLAGUE NOVARTIS’S PROPOSAL EVEN IF IT PREVAILS.**

### **A. Novartis misrepresents what the parties agree on.**

MSN does not agree on Novartis’s twist to a judgment that “MSN’s ANDA filing infringed claim 1 of the '918 patent under 35 U.S.C. § 271(e)(2)” if Novartis prevails on the merits. D.I. 514 at 2-3. Such an infringement finding should apply *only* to the product addressed at trial. MSN’s final judgment removes language that deems any future amendments/supplements to MSN’s ANDA infringing. That MSN’s ANDA product may be altered is unknown; an infringement judgment based on speculation would be inappropriate.

### **B. Novartis’s brief provides no legal support for a § 271(e)(4)(A) reset order.**

Across all its briefing, Novartis has *not* directed this Court to a single case holding that § 271(e)(4)(A) relief is available for an infringement finding on a non-Orange Book patent. This is now at least the *fourth* time that Novartis has relied on *Vanda* and/or *Janssen* to support its §

271(e)(4)(A) theories. *See* D.I. 214 at 19-20; *Novartis Pharms. Corp. v. MSN Pharms. Inc.*, Appeal No. 2024-2211, D.I. 23 at 47 (Fed. Cir. Aug. 20, 2024); D.I. 484 at 17. But Novartis fails to acknowledge that *Vanda* and *Janssen*, unlike the instant scenario, also involved at least one Orange Book patent. Here, the sole asserted '918 patent is *not* listed and the Hatch-Waxman framework does not apply. MSN is unaware of any prior application of § 271(e)(4)(A) to patents not listed in the Orange Book, nor is it aware of case law suggesting § 271(e)(2) infringement of an unlisted patent “necessitates,” (D.I. 514 at 1), a reset order under § 271(e)(4)(A). That result would be contrary to the introduction of § 271(e)(4)(A) during the Hatch-Waxman Amendments to the Patent Act, alongside its reference to the listing process, which *does*, indeed, suggest such relief is only available to Orange Book patents despite Novartis’s Congressional-intent arguments otherwise, (*id.* at 4). Indeed, MSN was *not* required to certify against the '918 patent. Only listed patents, *e.g.* Novartis’s '659 patent, are relevant to FDA in assessing MSN’s approval status. The '918 patent *could* give rise to an *eBay*-based injunction but not an FDA reset order.

**C. MSN did not waive its § 271(e)(4)(A) arguments.**

Novartis has been on notice since *at least* the filing of MSN’s Answer that MSN opposed the instant § 271(e)(4)(A) claim. *See, e.g.*, D.I. 33 at ¶ 136. That Novartis feels MSN never “directly disputed” the reset order issue, (D.I. 514 at 4-5), is not grounds for the waiver it alleges. It is simply untrue that MSN “had never made this argument in the nearly 3 years of this case,” (*id.* at 4); MSN addressed this issue in its injunction briefing, (D.I. 500 at 17). Waiver arguments fail where allegations regarding the parties’ briefing are “squarely contradicted by the record.” *See Consol Pa. Coal Co., LLC v. Mahalaxmi Continental Ltd.*, 2024 WL 510518, at \*4 n.8 (3d Cir. Feb. 9, 2024). Even so, MSN notes that the instant briefing is the first chance for MSN to address whether § 271(e)(4)(A) relief should be *in a final judgment*. MSN cannot waive an argument related to a nascent issue; MSN timely objected to Novartis’s new argument.

Dated: July 10, 2025

Respectfully submitted,

/s/ Richard C. Weinblatt

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